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(54) Title: BLOOD REGULATION DEVICE

(57) Abstract: The present invention relates to a cardiovascular stent including a generally tubular body and a synthetic valve capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.

T	"Blood Regulation Device
2	
3	The present invention relates to stents for
4	connecting a first compartment to a second
5	compartment. In particular, the invention relates
6	to cardiovascular stents e.g. for connection of the
7	left ventricle of the heart to a coronary artery.
8	
9	Coronary artery disease is a major problem thoughout
10	the world, particularly in Western society.
11	Coronary arteries, as well as other blood vessels,
12	can become clogged with plaque, impairing the
13	efficiency of the heart's pumping action. This can
14	lead to heart attacks, angina and death.
15	
16	A number of methods are used to treat clogged
17	coronary arteries such as bypass operations or
18	balloon angioplasty.
19	
20	In bypass operations one or more venous segments are
21	inserted between the aorta and the coronary arteries
22	to bypass the blocked portion of the coronary artery
23	such that an unobstructed flow of blood and thus

1 blood supply to the heart is achieved. More than 500,000 bypass procedures are performed in the US 2 3 every year. 4 However, bypass surgery is a very intrusive 5 procedure requiring expensive and time-consuming 6 7 surgery. During a bypass operation, an incision is made through the patient's skin and the patient is 8 placed on a bypass pump such that the heart can be 9 operated on, while it is not beating. A saphenous 10 11 vein graft is harvested from a patient's leg and the 12 vein is then grafted into position between the aorta 13 and the coronary artery to allow unobstructed blood flow. This surgery is both traumatic to the patient 14 15 and requires a substantial period of time in 16 hospital and prolonged convalescence. 17 18 In some circumstances a balloon angioplasty 19 procedure is used instead of the above method, to 20 treat coronary artery plaque occlusion. case a deflated balloon catheter is placed within 21 22 the narrowed segment of the coronary artery. 23 balloon is then inflated to a high pressure, transmitting circumferential pressure to the plaque 24 25 occluding the artery, compressing the plaque and 26 thus increasing the diameter through which blood can 27 flow. 28 Although balloon angioplasty is minimally invasive, 29 30 this procedure can only be used in a limited number

3132

of circumstances.

1 In addition to the two techniques discussed above, 2 which have been traditionally used to treat coronary 3 artery occlusion, a more recent procedure allows a stent to be positioned between the coronary artery 4 and the left ventricle of the heart such that blood 5 can flow unobstructed from the left ventricle of the 6 7 heart to the coronary artery, bypassing the occluded 8 portion of the coronary artery. The stent may be positioned between the left ventricle of the heart 9 10 and the coronary artery using a less invasive procedure than that required for coronary bypass 11 12 surgery. 13 Typically the stent is a conduit with a passage 14 extending longitudinally therethrough. Generally a 15 stent is cylindrical in cross section and is 16 17 generally an elongate tube. 18 19 A disadvantage of providing a stent extending from the left ventricle of the heart to the coronary 20 artery is that during diastole blood may reflux from 21 the coronary artery back into the left ventricle of 22 23 the heart. Such refluxes of blood are undesirable. 24 Some reports have indicated that backflow of 25 oxygenated blood back into the left ventricle 26 27 chamber of the heart during diastole can cause the 28 the myocardium to receive an inadequate supply of 29 blood. This can lead to the myocardium becoming Indeed, some studies have suggested that ischemic. 30 measurement of the blood flow during systole and the 31 32 backflow during diastole indicates that only a 30

1	percent net flow rate of blood from the left
2	ventricle chamber into the artery is achieved
3	following introduction of a stent between the two
4	compartments.
5	
6	There remains a need for improved (more efficient)
7	stents.
8	•
9	The present inventor has overcome a number of
10	problems of stents of the prior art.
11	
12	According to a first aspect of the present invention
13	there is provided a cardiovascular stent comprising
14	a generally tubular body and a synthetic one-way
15	valve capable of moving from a first open position
16	to a second closed position, wherein, in use,
17	movement of fluid, e.g. blood, in a first direction
18	through the stent causes the valve to adopt the open
19	position and movement of fluid in a second opposite
20	direction causes the valve to adopt the closed
21	position.
22	•
23	The valve is deemed to be in the closed position
24	when it restricts the passage of fluid in the second
25	direction e.g. from a second compartment to a first
26	compartment. A stent as described by the present
27	invention can be used to enable the movement of
28	fluid from a proximal position in a first
29	cardiovascular compartment to a distal position in
30	the same cardiovascular compartment or a different
31	cardiovascular compartment.
32	

Preferably in the closed position, the valve allows 1 2 movement of fluid in the second direction of less 3 than 40% that when the valve is in the open 4 position. 5 6 More preferably in the closed position the valve 7 allows movement of fluid in a second direction of less than 30%, preferably less than 20%, even more 8 9 preferably less than 10%, even more preferably less 10 than 5%, even more preferably less than 2% and most preferably less than 1% that when the valve is in 11 12 the open position. 13 14 A stent with a synthetic valve is advantageous as it 15 can restrict the passage of fluid in a second 16 direction, e.g. from a second compartment to a first 17 compartment, e.g. from a coronary artery to the left ventricle of the heart. This provides for an 18 19 increase in the net flow rate of blood from the 20 first compartment into the second compartment and 21 minimises the likelihood of e.g. the myocardium, of 22 which the coronary artery provides the blood supply, receiving an inadequate supply of blood. 23 24 25 In such an embodiment the movement of fluid in the first direction e.g. from the first compartment to 26 27 the second compartment causes a pressure difference across the valve sufficient to cause the valve to 28 adopt the open position. Fluid flow in the second 29 opposite direction, e.g. from the second compartment 30 31 to the first compartment across the valve, causes

the valve to adopt the closed position.

1	
2	Further, the use of a synthetic valve has the
3	further advantage that a vein does not need to be
4	harvested from the patient.
5	
6	Preferably in the absence of movement of fluid in
7	either a first or second direction the valve adopts
8	the closed position. Thus preferably the valve is
9	resiliently biased towards the closed configuration.
10	
11	Preferably the stent is for use in linking
12	cardiovascular compartments.
13	
14	Preferably the first compartment is a first
15	cardiovascular compartment and the second
16	compartment is a second cardiovascular compartment.
17	
18	A cardiovascular stent is a stent suitable for use
19	to link one part of a cardiovascular compartment to
20	another part of the same cardiovascular compartment
21	or to another cardiovascular compartment.
22	
23	A cardiovascular compartment is defined as any organ
24	or any structure of the circulatory system including
25	an artery, vein or chamber of the heart.
26	
27	In a preferred embodiment the stent is for use as a
28	stent between the left ventricle of the heart and a
29	coronary artery.
30	
31	Preferably the valve is formed from resilient
32	material.

1 2 A valve formed from resilient material is 3 advantageous as it requires few mechanical 4 components to enable the valve to move between the 5 open and closed positions and thus there is less 6 likelihood of damage to red blood corpuscles moved 7 through the stent. 8 9 Preferably the flexible resilient material is a 10 suitable biostable biocompatible polymer. 11 12 Preferably the flexible resilient material includes Elast-Eon<sup>TM</sup>, Biomer or Biospan. 13 14 Details of the polymer  ${\tt Elast-Eon^{TM}}$  can be found in 15 WO98/13405, WO92/00338, WO92/09467, WO99/01496. 16 17 18 In an embodiment in which the valve is formed from resilient material, in the closed position, 19 preferably at least a portion of the aperture formed 20 21 by the resilient material of the valve is ellipsoidal shape in cross-section. 22 ellipsoidal shape restricts blood flow from the 23 24 second cardiovascular compartment into the first 25 cardiovascular compartment. 26 27 Preferably the valve is constructed such that movement of fluid such as blood in the first 28 direction through the stent urges the resilient 29 material of the valve to adopt a configuration in 30 which the aperture defined by the material is 31 32 substantially circular in cross-section thereby

1	enabling increased fluid to flow through the valve
2	and thus through the stent. Hence, with the
3	circular aperture increased flow from the first
4	cardiovascular compartment into the second
5	cardiovascular compartment is provided.
6	
7 `	In an alternative embodiment the valve may comprise
8	at least two leaflets formed from resilient material
9	which when fluid is flowing in the second direction
10	through the stent or when no fluid is flowing
11	through the stent, the leaflets are urged towards
12	each other such that the passage of fluid e.g. blood
13	is minimised. In this embodiment, movement of fluid
14	in the first direction e.g. from a first compartment
15	to a second compartment urges the leaflets of the
16	valve to move apart from each other enabling the
17	passage of fluid through the stent.
18	
18 19	The valve may be located at any position in the
	The valve may be located at any position in the stent.
19	
19 20	
19 20 21	stent.
19 20 21 22	stent.  Preferably the valve is located at either end of the
19 20 21 22 23	stent.  Preferably the valve is located at either end of the
19 20 21 22 23 24	Preferably the valve is located at either end of the stent.
19 20 21 22 23 24 25	Preferably the valve is located at either end of the stent.  Such an embodiment is advantageous as a valve
19 20 21 22 23 24 25 26	Preferably the valve is located at either end of the stent.  Such an embodiment is advantageous as a valve portion of the stent can extend into a
19 20 21 22 23 24 25 26 27	Preferably the valve is located at either end of the stent.  Such an embodiment is advantageous as a valve portion of the stent can extend into a cardiovascular compartment. This can be of
19 20 21 22 23 24 25 26 27 28	Preferably the valve is located at either end of the stent.  Such an embodiment is advantageous as a valve portion of the stent can extend into a cardiovascular compartment. This can be of importance, for example, if the stent is for use
19 20 21 22 23 24 25 26 27 28 29	Preferably the valve is located at either end of the stent.  Such an embodiment is advantageous as a valve portion of the stent can extend into a cardiovascular compartment. This can be of importance, for example, if the stent is for use between the left ventricle of the heart and the

1 2 Preferably the valve is integral to the stent. 3 4 Although a stent may be located and then valve means 5 provided on the stent, it is preferable if the stent 6 and valve are provided in one unit such that they 7 can be located between the cardiovascular 8 compartments in a single procedure. 9 10 The stent may be constructed of any suitable 11 material. 12 13 The stent may comprise a suitable rigid 14 biocompatible metal which may include, but is not limited to one or more of stainless steel, spring 15 16 steel, Nitinol and / or a flexible resilient 17 material. 18 19 Preferably the stent may be constructed from 20 scaffold mesh. 21 22 Preferably the stent comprises a flange portion 23 located towards or at one end of the stent. 24 25 This is advantageous as when the stent is pushed into tissue to provide a passage between two 26 27 compartments the depth of the stent in the tissue 28 can be controlled by the flange portion. If, for example, the flange portion is towards or at the 29 30 rear portion of the stent, the front portion being 31 the portion inserted first into the tissue, on 32 pushing the stent into tissue from one compartment

to another the flange provided at the rear will

prevent the stent being pushed too far into the

tissue, ensuring that the lumen of the stent extends

from a first compartment into a second compartment.

5 Moreover the flange portion can also be used to

6 secure the stent in position, the tissue at around

7 the flange preventing movement of the stent from a

8 first compartment to a second compartment.

In a preferred embodiment, the valve comprises at least one cantilever member, having a first end and a second end, said cantilever member being pivoted at said first end to the stent, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is open. In a preferred example of such an embodiment when the second end of the cantilever member is in the extended position the material forming the valve and defining the aperture of the valve, when in the open position, is pulled such that the area of the aperture formed by the material is decreased.

In such a preferred example of this embodiment, movement of fluid in a first direction through the stent causes the second end of the cantilever member to resiliently move radially inwards towards the central longitudinal axis of the stent. This movement of the second end of the cantilever member causes the material forming the valve and defining the aperture of the valve to form a larger aperture (preferably substantially circular) in cross section

1 enabling increased fluid to flow through the valve. As the fluid flow in the first direction is reduced 2 or when there is no fluid flow in the first 3 direction, the cantilever member resiliently pivots 4 5 to the extended position. This movement of the second end of the cantilever member to the extended 6 7 position causes the material forming the valve and 8 defining the aperture of the valve to be pulled to 9 form an aperture of reduced area in cross section. 10 As the aperture has less area in cross section than 11 the substantially circular aperture, fluid flow in both the first and second directions is restricted. 12 13 More preferably, the valve comprises two cantilever 14 In this embodiment the two cantilever 15 16 members are resiliently pivoted at first ends of the 17 members to the stent. When no fluid is flowing 18 through the stent the second ends of the cantilever 19 members pivot radially outwards to an extended 20 position. Preferably radially greater than the circumference of the stent. When the second ends of 21 the cantilever members are in the extended positions 22 the material forming the valve and defining the 23 aperture of the valve when in the open position is 24 held such that the area of the aperture formed by 25 26 the material is decreased and forms and ellipsoid in 27 cross section. 28 29 Such an embodiment may function as follows: Movement 30 of fluid in a first direction through the stent 31 causes the second ends of the cantilever members to 32 resiliently move radially inwards towards the

Т	central longitudinal axis of the stent. This
2	movement of the second ends of the cantilever
3	members causes the material forming the valve and
4	defining the aperture of the valve to form a
5	substantially circular aperture in cross section
6	enabling blood to flow through the valve.
7	
8	As the fluid flow in the first direction is reduced,
9	or when there is no fluid flow in the first
10	direction, the second ends of the cantilever members
11	again resiliently pivot to an extended position.
12	The movement of the second ends of the cantilever
13	members to their extended positions again causes the
14	material forming the valve and defining the aperture
15	of the valve to be pulled to form an ellipsoid
16 .	aperture of reduced area in cross section. As the
17	aperture has less area in cross section than the
18	substantially circular aperture, fluid flow in both
19	the first and second directions is restricted.
20	
21	With the circular cross section increased flow
22	through the stent is enabled and with the
23	ellipsoidal cross section flow in the second
24	direction is minimised.
25	
26	In such an embodiment, the aperture formed by the
27	resilient material is preferably pulled from a
28	substantially circular cross section to a
29	substantially ellipsoidal cross section, which, in
30	use, restricts the flow of fluid from a second
31	compartment toward a first compartment.
32	

Preferably the stent is constructed such that it can 1 2 be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, 3 4 wherein, in the collapsed configuration, the stent 5 is of narrower diameter that in the expanded configuration. 6 7 8 Such a structure enables the stent to be suitably 9 placed in the body in the narrowed collapsed 10 configuration and then expanded from its collapsed 11 configuration to a fully expanded configuration. 12 The diameter of the stent can be increased from the 13 collapsed to expanded position using any suitable 14 15 procedures, for example, using a balloon angioplasty procedure. 16 17 In order to position such a stent, the stent, in a 18 19 collapsed position, may be delivered to the desired 20 location in the body, for example, the heart muscle between the left ventricle and a coronary artery on 21 22 a catheter. The suitably located stents may then be deployed by expanding a balloon placed in the stent 23 24 such that the diameter of the stent increases from that of the collapsed stent position to the 25 26 increased diameter of the stent in the expanded 27 position. 28 Further to expanding the diameter of the stent by 29 30 the balloon the stent locks in the expanded 31 position, holding the stent against the heart muscle

1	and maintaining the stent in its expanded position
2	with increased diameter.
3	`
4	The collapsed stent can be placed by suitable
5	minimally invasive techniques such as percutaneous
6	delivery.
7	
8	In an alternative embodiment the stent may be
9	constructed of material with memory such that once
10	suitably placed in the body the diameter of the
11	stent expands from a collapsed position to a fully
12	expanded position.
13	
14	For example, in such an embodiment, the stent may
15	adopt a collapsed position at low temperatures, for
. 16	example temperatures below body temperature, but an
17	expanded position at body temperature.
18	
19	In one preferred embodiment, the valve of the stent
20	is moved to a closed position on increasing the
21	diameter of the stent from a collapsed position to
22	an expanded position when the stent is suitably
23	positioned in the body.
24	
25	In particularly preferred embodiments the valve
26	comprises at least one cantilever member as
27	discussed above. Expansion of diameter of the stent
28	e.g. on deployment of the stent, causes the valve to
29	adopt the closed configuration.
30	
31	In this embodiment, the cantilever member may be
32	resiliently pivoted at a first end to the stent such

1	that on expansion of the diameter of the stent a
2	second end of the cantilever member pivots to an
3	extended position in which the material forming the
4	valve and defining the aperture of the valve when in
5	the open position is pulled such that the area of
6	the aperture formed by the material is decreased.
7	
8	More preferably the valve comprises two cantilever
9	members which, on deployment of the stent, cause the
10	diameter of the stent to expand from a collapsed
11	configuration in which the valve portion of the
12	stent is in an open position to an expanded
13	configuration in which the valve is in a closed
14	position. With the circular cross section increased
15	flow through the stent is enabled and with the
16	ellipsoidal cross section flow in the second
17	direction is minimised.
18	
19	In such an embodiment, the aperture formed by the
20	resilient material is preferably pulled from a
21	substantially circular cross section to a
22	substantially ellipsoidal cross section, which, in
23	use, restricts the flow of fluid from a second
24	compartment toward a first compartment.
25	
26	The diameter and length of the stent depends on its
27	use. For example, the stent may be of suitable
28	length to extend between the left ventricle of heart
29	and coronary artery.
30	
31	Preferably the stent is two to fifteen millimetres
32	in diameter.

1 2 The stent may be constructed such that a number of 3 stents may be positioned "end to end" to increase the effective length of the stent arrangment. 4 5 6 Thus, in one preferred embodiment the stent is 7 resiliently deformable at at least one end to 8 receive and enable connection with a second stent. 9 10 In an alternative embodiment the stent may be shaped at one or both ends to enable connection to a second 11 12 stent. 13 The stent may comprise drug coatings or chemical and 14 / or mechanical coatings such as a TEFLON ™ membrane 15 16 to minimise stenosis. 17 18 As described above, stents of the present invention may be used to link or repair two cardiovascular 19 20 compartments. 21 For example, stents of the invention may be used to 22 23 link a coronary artery to the left ventricle of the heart. 24 25 26 Stents of the present invention may also be used in 27 non coronary structures e.g. non coronary veins and 28 / or arteries. 29 30 For example, the stents may be used to link a first 31 portion of an ascending venous structure such as the 32 saphenous vein and a second portion of the same

1	ascending venous structure. If the region between
2	the first and second portions of the femoral artery
3	is damaged or occluded, a stent of the invention may
4	be located between the first and second portions to
5	enable the movement of blood from the first portion
6	to the second portion.
7	
8	Thus in use, a stent of the present invention may be
9	provided between a first and second portion of a
10	vein e.g. a saphenous vein, to allow blood to flow
11	from the first portion to the second portion, but
12	restrict blood flow from the second portion to the
13	first portion. Such an arrangement could be used to
14	treat varicose veins.
15	
16	In a second aspect of the present invention there is
17	provided a method for treating a full or partial
18	occlusion of a blood vessel comprising the step of
19	·
20	providing stent means wherein said stent means
21	comprise at least one stent of the first aspect
22	of the invention,
23	
24	a first end of the lumen of the stent means
25	being in communication with a cardiovascular
26	compartment on one side of the occlusion,
27	
28	the second end of the lumen of the stent means
29	being in communication with a cardiovascular
30	compartment on the other side of the occlusion
31	allowing blood flow from the first side to the

1	second side of the cardiovascular compartment
2	through the lumen of the stent means.
3	
4	The cardiovascular compartments on each side of the
5	occlusion may be in same the blood vessel in which
6	the occlusion is present.
7	
8	In alternative embodiments the cardiovascular
9	compartments may be different compartments, for
10	example the left ventricle of the heart and a
11	coronary artery.
12	
13	The stent means may comprise a single stent.
14	Alternatively the stent means may comprise a
15	plurality of stents longitudinally aligned to allow
16	the flow of blood from a stent at a first end of the
17	stent means to a stent at a second end of the stent
18	means.
19	
20	Preferably the stent means comprise a single stent
21	of the first aspect of the invention.
22	
23	In preferred embodiments the method further
24	comprises the step of positioning the stent means
25	between the compartments, increasing the diameter of
26	the stent means from a reduced diameter in a
27	collapsed position to an increased diameter in an
28	expanded position.
29	
30	In particularly preferred embodiments the method
31	comprises the steps of
32	

1	inserting the stent into position between a
2	first cardiovascular compartment and a second
3	cardiovascular compartment;
4	
5	expanding the diameter of the stent such that
6	the valve is moved to the closed position, but
7	can move to the open position when fluid flows
8	in a first direction from a first
9	cardiovascular compartment to a second
10	cardiovascular compartment.
11	
12	According to a further aspect of the invention there
13	is provided a method for treating varicose veins
14	comprising positioning stent means comprising at
15	least one stent of the first aspect of the invention
16	in a vein or replacing all or part of a vein with
17	stent means comprising at least one stent of the
18	first aspect of the invention.
19	
20	As above, stent means may comprise a plurality of
21	stents longitudinally aligned to allow the flow of
22	fluid from a stent at a first end of the stent means
23	to a stent at a second end of the stent means.
24	
25	As described above, in a preferred embodiment of a
26	first aspect of the invention a stent comprising a
27	valve comprising at least one cantilever member is
28	provided. The use of such a valve is not limited to
29	uses within the body. Accordingly, in a further
30	independent aspect there is provided tube means,
31	said tube means comprising a valve which comprises
32	at least one cantilever member, having a first end

1	and a second end, said cantilever member being
2	pivoted at said first end to the tube, the
3	cantilever member being resiliently pivotable from a
4	first extended position in which the valve is in a
5	closed position to a second position in which the
6	valve is open.
7	
8	Tubes comprising such valves may be used to link a
9	first cardiovascular compartment with a compartment
10	in a cardiovascular device or vice versa.
11	
12	In a further embodiment tubes comprising such valves
13	may be used to link first and second compartments in
14	a device to transport fluid, for example blood.
15	
16	For example, such tubes comprising at least one
17	cantilever member can be used in machines or devices
18	used to move fluid, for example blood, such as
19	dialysis machines.
20	
21	A further independent aspect of the present
22	invention is a device for the movement of fluid.
23	
24	Preferably the fluid is blood.
25	
26	The present invention will now be described, by way
27	of example only, with reference to the accompanying
28	figures in which;
29	
30	Figure 1 is an illustration of an embodiment of
31	a stent of the present invention extending from

1	the left ventricle of the heart into the
2	coronary artery;
3	
4	Figure 2 is an enlarged view of an embodiment
5	of a stent of the present invention connecting
6	the left ventricle of the heart to the coronary
7	artery;
8	
9	Figure 3 is an illustration of an embodiment of
10	a stent of the present invention wherein a
11	second end of the stent is in a closed
12	position;
13	
14	Figure 4 (A) is an illustration of an
15	embodiment of a stent in a collapsed form, (B)
16	is an illustration of an embodiment of a stent
17	of the present invention in an expanded form;
18	
19	Figure 5 is an illustration of an embodiment of
20	a stent of the present invention where a second
21	end of a stent is in an open position;
22	
23	Figure 6 is an illustration of at least two
24	embodiments of stents of the present invention
25	aligned along their longitudinal axes such that
26	blood can flow from the lumen of a first stent
27	to the lumen of a second adjacent stent; and
28	
29	Figure 7 is an illustration of stents according
30	to an embodiment of the present invention
31	aligned along their longitudinal length wherein
32	the first stent has a shaped end to receive the

1	second stent and another stent is deformable to
2	receive a stent inside one end.
3	
4	As shown in figure 1, the coronary artery 10 is
5	known to branch off the aorta 12 and be positioned
6	along the external surface of the heart wall 14.
7	
8	Following oxygenation of the blood, the oxygenated
9	blood flows from the heart 16 into the aorta 12 and
10	onto the rest of the body. Some of the oxygenated
11	blood is circulated along the coronary artery 10 in
12	order to oxygenate the muscles of the heart. In
13	some individuals an occlusion is formed within the
14	coronary artery due to plaque build up. These
15	occlusions can lead to a variety of symptoms and
16	diseases ranging from mild angina to heart attack.
17	
18	In order to allow blood flow around the occlusion
19	within the coronary artery and to at least partially
20	restore the flow of oxygenated blood through the
21	coronary artery, it is possible to bypass the
22	blocked portion of the coronary artery by providing
23	a stent 18 which extends from the left ventricle 20
24	of the heart into the coronary artery 10, as shown
25	in figure 2. Location of the stent 18 as shown in
26	figure 2 allows blood to flow unobstructed from the
27	left ventricle 20 of the heart to the coronary
28	artery 10.
29	
30	Allowing blood flow past or around occlusions of the
31	coronary artery 10 using a stent 18 is preferable to
32	traditional bypass surgery in that the stent 18 may

1 be located and fitted using minimally invasive techniques. Generally the stents previously used to 2 3 connect the left ventricle 20 of the heart to the coronary artery 10 are stents formed by hollow tubes 4 5 comprising biocompatible material such as titanium alloys, nickel alloys or biocompatible polymers. 6 7 These tubes may be provided and located between the 8 left ventricle 20 of the heart and the coronary artery 10 in a collapsed position and when suitably 9 located, expanded from a collapsed position to a 10 11 fully expanded position, using an inflatable balloon 12 catheter or other method. 13 14 Although such stents allow the flow of blood from the left ventricle 20 of the heart into the coronary 15 16 artery, no artificial or mechanical means are present on conventional stents to restrict the 17 18 backflow of blood. 19 20 As shown in figure 3, a stent of the present invention is provided with a synthetic valve 22, one 21 example of the valve being a portion of flexible 22 resilient material located at the second end 24 of 23 the stent. This flexible resilient material is 24 25 preferably integral with the rest of the stent. 26 27 The valve may be formed during manufacture of the 28 stent, prior to insertion of the stent into the 29 body. 30 31 Alternatively, as shown in the embodiment of the

stent in figure 4, the valve can be created by the

pivotal movement of cantilever members during the 1 movement of the stent from a collapsed position to 2 an expanded position, while the stent is located in 3 the body. 4 5 As shown in figure 4a, in this embodiment, in a 6 collapsed position, the resilient material, held by 7 two cantilever members 21, forms a substantially 8 cylindrical aperture 28. 9 10 The cantilever members are conjoined to the stent at 11 a first end only and from the rigid biocompatible 12 metal portion 23 of the stent. On deployment 13 (expansion of diameter) of the stent, the second 14 ends of the cantilevers move away from each other to 15 an extended position. This movement pulls the 16 resilient material such that its cross sectional 17 shape is changed from substantially circular to 18 substantially ellipsoidal. The change in the cross 19 sectional shape restricts the flow of blood in a 20 second direction from the second compartment into 21 the first compartment through the stent. Blood flow 22 through the stent from a first compartment to a 23 second compartment causes the material of the 24 leaflets to be pushed such that the cantilever 25 members resiliently move towards each other and the 26 aperture of the valve becomes substantially circular 27 in cross section. The area of the circular cross 28 section is larger that the ellipsoidal cross section 29 and blood can thus easily flow from the first 30 compartment to the second compartment. During 31 diastole, when blood is not being pushed from the

1	first compartment to the second compartment, the
2	pressure of the blood on the material of the valve
3	decreases. The second ends of the resilient
4	cantilever members can again move away from each
5	other and cause the valve material to form an
6	ellipsoidal cross section.
7	
8	It can be appreciated that if more than two
9	cantilevers are used for example, three, four or
10	five cantilevers, then on deployment, the cross
11	sectional shape will not be elliptical, but
12	substantially triangular, rectangular or pentacle
13	shaped. Different shaped openings may be used as
1.4	appropriate to restrict the flow of blood from the
15	second compartment to the first compartment. In
16	addition, different shaped openings can be chosen to
17	minimise, pressure on the arterial wall caused by the
18	cantilever members.
19	
20	In one embodiment, a valve formed from resilient
21	material does not require expansion of the diameter
22	of the stent to cause the resilient material to
23	adopt the closed position. In this embodiment
24	cantilever members are not required to pull the
25	material of the valve to a closed position and the
26	valve is manufactured in the closed position. Blood
27	flow in a first direction from the first compartment
28	towards the second compartment causes the resilient
29	material to adopt an open position.
30	
31	In addition to the cantilever members disclosed
32	herein, different methods of urging the resilient

material to a closed position following expansion of 1 a stent structure from a collapsed position can be 2 envisaged. 3 4 During systole (contraction of the heart) the blood 5 is pumped by the heart through the stent 18 from the 6 first end 26 located at the left ventricle 20 of the 7 heart towards the second end 24 of the stent located 8 at the coronary artery. On contraction of the 9 heart, the blood of the left ventricle of the heart 10 is moved in a first direction through the stent 11 causing the valve to move from an ellipsoidal shape. 12 (closed position) to an open (circular cross 13 sectional shape) position. 14 15 In the closed position the ellipsoidal shape causes 16 the area through which blood can flow from the 17 second compartment to the first compartment to be 18 reduced to 10% the area of the open position of the 19 valve. The backflow of blood is thus reduced when 20 blood is not being pumped through the stent from the 21 first compartment to the second compartment. 22 23 Typically reflux of blood through the valve from the 24 second compartment to the first compartment may be 25 25% that which would be expected if the valve is in 26 the open position. 27 28 The movement of the resilient material in this 29 manner, from an ellipsoidal shape (closed position) 30 towards a circular shape (open position), increases 31 the area of the aperture 28 through which the blood 32

1	can flow from the first compartment (in this case
2	the left ventricle of the heart) into the second
3	compartment (in this case the coronary artery) and
4	allows the unobstructed flow of blood through the
5	valve.
6	·
7	As the pressure of the blood flow through the valve
8	in a first direction decreases, the resilient
9	material is urged by the material (and in particular
10	embodiments the cantilever members of the rigid
11	portion of the stent) to cause the valve to adopt a
12	resting position, wherein the aperture of the valve
13	into the coronary artery forms an ellipsoidal shape.
14	This change in shape of the aperture reduces the
15	area of the aperture located at the second
16	compartment and minimises the blood flow from the
17	coronary artery into the left ventricle of the
18	heart.
19	
20	Movement of the stent from a collapsed position to
21	an expanded position causes the stent to be gripped
22	by the heart muscle. A flange or other projection
23	may also be provided on the stent to aid location of
24	the stent.
25	
26	As shown in figures 6 and 7 at least two stents can
27	be aligned along their longitudinal axes such that
28	blood can be communicated from the lumen of a first
29	stent to the lumen of a second adjacent stent. By
30	aligning several stents together, blood may be moved
31	from a first proximal position to a second distal
32	position, either between two different

1	cardiovascular compartments such as the left		
2	ventricle of the heart and a coronary artery or		
3 .	within the same cardiovascular compartments such as		
4	a blood vessel.		
5			
6	By aligning a number of stents along their		
7	longitudinal axis it is possible to allow blood flow		
8	to be effected over a relatively large distance. In		
9	addition, as each of the stents comprise a valve,		
10	the stents more closely mimic the situation in		
11	actual veins preventing the backflow of blood and		
12	allowing blood to be moved upwards. An example of		
13	when the blood may be required to be moved upwards		
14	is in the leg of a patient when said patient is		
15	standing.		
16			
17	The valves present on each of the stents allow blood		
18	to be pushed through the valve on contraction of the		
19	heart, but minimise the backward movement of the		
20	blood during diastole. This allows blood to be		
21	moved up the leg and through the body.		
22			
23	To allow the stents to be conjoined to each other, a		
24	first end of a stent may be capable of deformation		
25	(as shown in figure 7 (30)) to allow a second stent		
26	to be partially inserted therein. Alternatively or		
27	additionally the stent may also be widened (figure $7$		
28	(32)) to allow ingress of a second stent as shown in		
29	figure 7.		
30			
31	It can be appreciated that various improvements and		
32	modifications can be made without departing from the $% \left( 1\right) =\left( 1\right) \left( 1\right) $		

1	scope of the present invention. In particular it
2	can be envisaged that the valve may be formed from
3	at least two leaflets, which in a resting position
4	are urged towards each other minimising blood flow
5	from the second cardiovascular compartment into the
6	first cardiovascular compartment. On movement of
7	blood in a first direction through the stent, from
8	the first compartment to the second compartment,
9	these leaflets may be pushed apart from each other,
10	enabling blood flow from the first compartment into
11	the second compartment. During diastole the two
12	leaflets of the valve will be urged towards each
13	other due to the resilience of the material.
14	Alternatively, different methods may be used to
15	align the stents along their longitudinal length
16	such as providing junction means.
17	

1	Clai	Claims		
2				
3	1.	A cardiovascular stent comprising:		
4		a generally tubular body, and		
5		a synthetic one-way valve capable of moving		
6		from a first open position to a second closed		
7		position, wherein, in use, movement of fluid in		
8		a first direction through the stent causes the		
9		valve to adopt the open position and movement		
10		of fluid in a second opposite direction causes		
11		the valve to adopt the closed position.		
12				
13	2.	A cardiovascular stent as claimed in claim 1		
14		wherein the valve is formed from resilient		
15		material.		
16				
17	3.	A cardiovascular stent as claimed in claim 2		
18		wherein the valve is constructed such that, in		
19ุ		use, movement of fluid in the first direction		
20		through the stent urges the resilient material		
21		of the valve to adopt a configuration in which		
22		the aperture defined by the material is		
23		substantially circular in cross-section thereby		
24		enabling increased fluid to flow through the		
25		valve and thus through the stent.		
26	•			
27	4.	A cardiovascular stent as claimed in claim 2 or		
28		3 wherein the valve comprises two leaflets		
29		formed from resilient material and wherein, in		
30		use, when fluid is flowing in the second		
31		direction through the stent or when no fluid is		
32		flowing through the stent, the leaflets are		

1		urged towards each other such that the passage
2		of fluid is minimised.
3		
4	5.	A cardiovascular stent as claimed in any one of
5		the preceding claims, wherein the valve
6		comprises at least one cantilever member having
7		a first end and a second end, said cantilever
8		member being pivoted at said first end to the
9		stent, the cantilever member being resiliently
LO		pivotable from a first extended position in
11.		which the valve is in a closed position to a
12		second position in which the valve is in the
13		open position.
14		
15	6.	A cardiovascular stent as claimed in claim 5
16		wherein the valve comprises two cantilever
17		members.
18		
19	7.	A cardiovascular stent as claimed in any one of
20		the preceding claims wherein the stent is
21		constructed such that it can be expanded in
22		diameter from a "collapsed" configuration to an
23		"expanded" configuration, wherein in the
24		collapsed configuration, the stent is of
25		narrower diameter than in the expanded
26		configuration.
27		$\cdot$
28	8.	A cardiovascular stent as claimed in claim 7
29		when dependent on claim 5 or claim 6 wherein on
30		expansion of the diameter of the stent, the
31		second end of the cantilever member pivots to
32		an extended position in which the material

1		forming the valve and delining the aperture of
2		the valve when in the open position is pulled
3		such that the area of the aperture formed by
4		the material is decreased.
5		·
6	9.	A cardiovascular stent as claimed in any one of
7		the preceding claims wherein the stent is
8		resiliently deformable at one or both ends to
9		receive and enable connection with a second
. 10		stent.
11		
12	10.	A cardiovascular stent as claimed in any of one
13		of the preceding claims wherein the stent is
14		shaped at one or both ends to enable connection
15		to a second stent.
16		
17	11.	A cardiovascular stent as claimed in any one of
18		the preceding claims for linking a coronary
19		artery to the left ventricle of the heart.
20		
21	12.	A cardiovascular stent as claimed in any one of
22		claims 1 to 10 for linking a first portion of
23		an ascending venous structure and a second
24		portion of the same ascending venous structure.
25		
26	13.	A method for treating a full or partial
27		occlusion of a blood vessel comprising the
28		steps of:
29		
30		providing stent means wherein said stent means
31		comprise at least one stent as claimed in
32		claims 1 to 12, a first end of the lumen of the

1		stent means being in communication with a
2		cardiovascular compartment on a first side of
3		the occlusion,
4		
5	•	the second end of the lumen of the stent means
6		being in communication with a cardiovascular
7		compartment on the other side of the occlusion
8		and allowing blood flow from the first side of
9		the occlusion to the other side of the
10		cardiovascular compartment through the lumen of
11		the stent means.
12		
13		
14	14.	A method as claimed in claim 13 wherein the
15		stent means comprises a plurality of stents-
16		longitudinally aligned to allow the flow of
17		blood from a stent at a first end of the stent
18		means to a stent at a second end of the stent
19		means.
20		
21	15.	A method as claimed in claim 13 or claim 14
22		further comprising the step of increasing the
23		diameter of the stent from a reduced diameter
24		in a collapsed position to an increased
25		diameter in an expanded position.
26		·
27	16.	A method for treating varicose veins comprising
28		the step of:
29		
30		positioning stent means comprising at least one
31		stent as claimed in claims 1 to 12 in a vein.
32		

1	17.	A method for treating varicose veins comprising
2		the step of:
3		
4		replacing at least a part of a vein with stent
5		means comprising at least one stent of the
6		first aspect of the invention.
·7		
8	18.	Tube means comprising a tubular portion and a
9		valve, said valve comprising at least one
1.0		cantilever member having a first end and a
11		second end, said cantilever member being
12		pivoted at said first end to the tubular
13		portion, the cantilever member being
14		resiliently pivotable from a first extended
15		position in which the valve is in the closed
16		position to a second position in which the
17		valve is in the open position.
18		
19	<sub>.</sub> 19.	Tube means as claimed in claim 18 wherein in
20		moving from the closed position to the open
21		position the aperture of the valve is moved
22		from being ellipisoidal to substantially
23		circular.
24		
25	20.	A device for moving fluid comprising a tube as
26	•	claimed in claims 18 or 19.
27		
28		

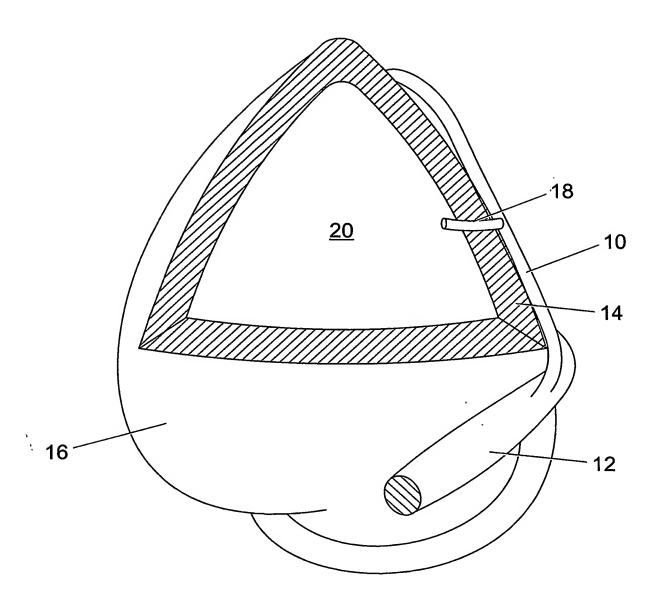


Fig. 1

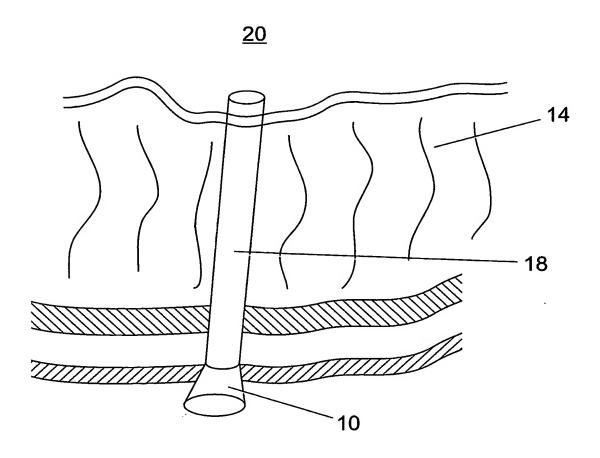


Fig. 2

3/7

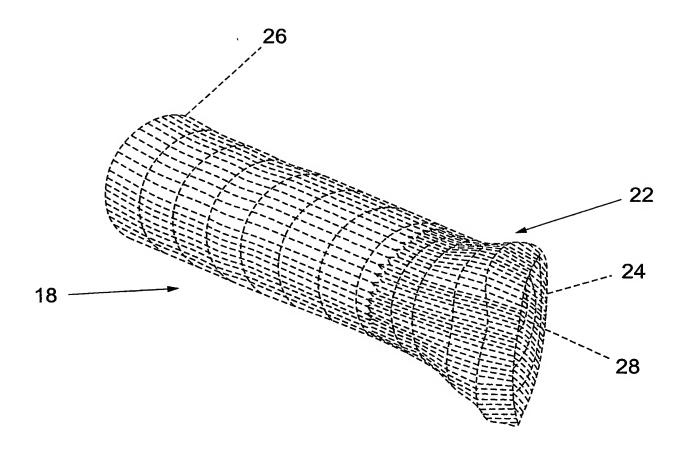
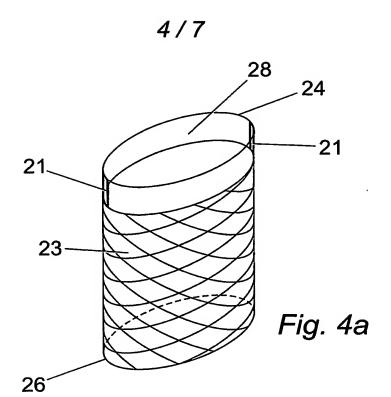
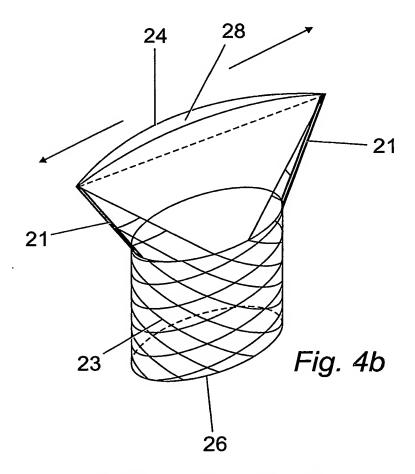


Fig. 3





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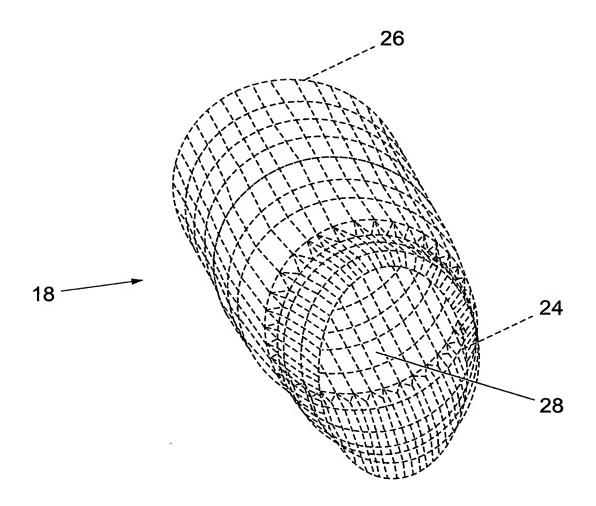


Fig. 5

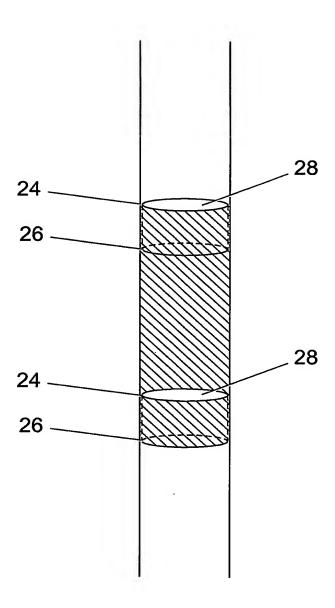


Fig. 6

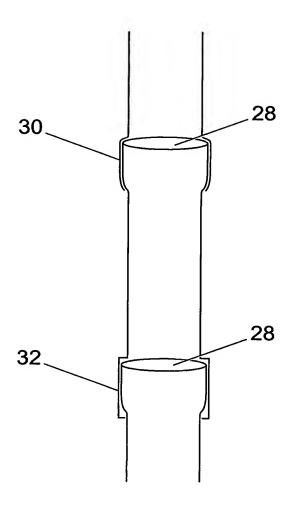


Fig. 7

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(54) Title: BLOOD REGULATION DEVICE

(57) Abstract: The present invention relates to a cardiovascular stent (18) including a generally tubular body and a synthetic valve (22) capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.



T	"Blood Regulation Device
2	
3	The present invention relates to stents for
4	connecting a first compartment to a second
5	compartment. In particular, the invention relates
6 .	to cardiovascular stents e.g. for connection of the
7	left ventricle of the heart to a coronary artery.
8.	
9	Coronary artery disease is a major problem thoughout
10	the world, particularly in Western society.
11	Coronary arteries, as well as other blood vessels,
12	can become clogged with plaque, impairing the
13	efficiency of the heart's pumping action. This can
14	lead to heart attacks, angina and death.
15	
16	A number of methods are used to treat clogged
17	coronary arteries such as bypass operations or
18	balloon angioplasty.
19	
20	In bypass operations one or more venous segments are
21	inserted between the aorta and the coronary arteries
22	to bypass the blocked portion of the coronary artery
23	such that an unobstructed flow of blood and thus

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1	blood supply to the heart is achieved. More than
2	500,000 bypass procedures are performed in the US
3	every year.
4	
5	However, bypass surgery is a very intrusive
6	procedure requiring expensive and time-consuming
7	surgery. During a bypass operation, an incision is
8	made through the patient's skin and the patient is
9	placed on a bypass pump such that the heart can be
LO	operated on, while it is not beating. A saphenous
11	vein graft is harvested from a patient's leg and the
12	vein is then grafted into position between the aorta
13	and the coronary artery to allow unobstructed blood
14	flow. This surgery is both traumatic to the patient
15	and requires a substantial period of time in
16	hospital and prolonged convalescence.
17	
18	In some circumstances a balloon angioplasty
19	procedure is used instead of the above method, to
20	treat coronary artery plaque occlusion. In this
21	case a deflated balloon catheter is placed within
22	the narrowed segment of the coronary artery. The
23	balloon is then inflated to a high pressure,
24	transmitting circumferential pressure to the plaque
25	occluding the artery, compressing the plaque and
26	thus increasing the diameter through which blood can
27	flow.
28	
29	Although balloon angioplasty is minimally invasive,
30	this procedure can only be used in a limited number
31	of circumstances.
32	

1	In addition to the two techniques discussed above,
2	which have been traditionally used to treat coronary
3	artery occlusion, a more recent procedure allows a
4	stent to be positioned between the coronary artery
5	and the left ventricle of the heart such that blood
6	can flow unobstructed from the left ventricle of the
7	heart to the coronary artery, bypassing the occluded
8	portion of the coronary artery. The stent may be
9	positioned between the left ventricle of the heart
10	and the coronary artery using a less invasive
11	procedure than that required for coronary bypass
12	surgery.
13	
14	Typically the stent is a conduit with a passage
15	extending longitudinally therethrough. Generally a
16	stent is cylindrical in cross section and is
17	generally an elongate tube.
18	
19	A disadvantage of providing a stent extending from
20	the left ventricle of the heart to the coronary
21	artery is that during diastole blood may reflux from
22	the coronary artery back into the left ventricle of
23	the heart. Such refluxes of blood are undesirable.
24	
25	Some reports have indicated that backflow of
26	oxygenated blood back into the left ventricle
27	chamber of the heart during diastole can cause the
28	the myocardium to receive an inadequate supply of
29	blood. This can lead to the myocardium becoming
30	ischemic. Indeed, some studies have suggested that
31	measurement of the blood flow during systole and the
32	backflow during diastole indicates that only a 30

1	percent net flow rate of blood from the left
2	ventricle chamber into the artery is achieved
3	following introduction of a stent between the two
4	compartments.
5	
6	There remains a need for improved (more efficient)
7	stents.
8	
9	The present inventor has overcome a number of
10	problems of stents of the prior art.
11	
12	According to a first aspect of the present invention
13	there is provided a cardiovascular stent comprising
14	a generally tubular body and a synthetic one-way
15	valve capable of moving from a first open position
16	to a second closed position, wherein, in use,
17	movement of fluid, e.g. blood, in a first direction
18	through the stent causes the valve to adopt the open
19	position and movement of fluid in a second opposite
20	direction causes the valve to adopt the closed
21	position.
22	
23	The valve is deemed to be in the closed position
24	when it restricts the passage of fluid in the second
25	direction e.g. from a second compartment to a first
26	compartment. A stent as described by the present
27	invention can be used to enable the movement of
28	fluid from a proximal position in a first
29	cardiovascular compartment to a distal position in
30	the same cardiovascular compartment or a different
31	cardiovascular compartment.
32	

Preferably in the closed position, the valve allows 1 movement of fluid in the second direction of less 2 3 than 40% that when the valve is in the open position. 4 5 6 More preferably in the closed position the valve 7 allows movement of fluid in a second direction of less than 30%, preferably less than 20%, even more 8 9 preferably less than 10%, even more preferably less than 5%, even more preferably less than 2% and most 10 11 preferably less than 1% that when the valve is in the open position. 12 13 A stent with a synthetic valve is advantageous as it 14 15 can restrict the passage of fluid in a second 16 direction, e.g. from a second compartment to a first 17 compartment, e.g. from a coronary artery to the left ventricle of the heart. This provides for an 18 increase in the net flow rate of blood from the 19 20 first compartment into the second compartment and minimises the likelihood of e.g. the myocardium, of 21 which the coronary artery provides the blood supply, 22 receiving an inadequate supply of blood. 23 24 In such an embodiment the movement of fluid in the 25 26 first direction e.g. from the first compartment to 27 the second compartment causes a pressure difference 28 across the valve sufficient to cause the valve to adopt the open position. Fluid flow in the second 29 opposite direction, e.g. from the second compartment 30 31 to the first compartment across the valve, causes the valve to adopt the closed position. 32

1 Further, the use of a synthetic valve has the 2 further advantage that a vein does not need to be 3 harvested from the patient. 4 5 Preferably in the absence of movement of fluid in 6 either a first or second direction the valve adopts 7 the closed position. Thus preferably the valve is 8 resiliently biased towards the closed configuration. 9 10 Preferably the stent is for use in linking 11 cardiovascular compartments. 12 13 Preferably the first compartment is a first 14 cardiovascular compartment and the second 15 compartment is a second cardiovascular compartment. 16 17 A cardiovascular stent is a stent suitable for use 18 to link one part of a cardiovascular compartment to 19 another part of the same cardiovascular compartment 20 or to another cardiovascular compartment. 21 22 A cardiovascular compartment is defined as any organ 23 or any structure of the circulatory system including 24 an artery, vein or chamber of the heart. 25 26 In a preferred embodiment the stent is for use as a 27 stent between the left ventricle of the heart and a 28 coronary artery. 29 30 Preferably the valve is formed from resilient 31 material. 32

1	
2	A valve formed from resilient material is
3	advantageous as it requires few mechanical
4	components to enable the valve to move between the
5	open and closed positions and thus there is less
6	likelihood of damage to red blood corpuscles moved
7	through the stent.
8	
9	Preferably the flexible resilient material is a
10	suitable biostable biocompatible polymer.
11	
12	Preferably the flexible resilient material includes
13	Elast-Eon <sup>TM</sup> , Biomer or Biospan.
14	
15	Details of the polymer $Elast-Eon^{TM}$ can be found in
16	WO98/13405, WO92/00338, WO92/09467, WO99/01496.
17	
18	In an embodiment in which the valve is formed from
19	resilient material, in the closed position,
20	preferably at least a portion of the aperture formed
21	by the resilient material of the valve is
22	ellipsoidal shape in cross-section. This
23	ellipsoidal shape restricts blood flow from the
24	second cardiovascular compartment into the first
25	cardiovascular compartment.
26	
27	Preferably the valve is constructed such that
28	movement of fluid such as blood in the first
29	direction through the stent urges the resilient
30	material of the valve to adopt a configuration in
31	which the aperture defined by the material is
32	substantially circular in cross-section thereby

enabling increased fluid to flow through the valve 1 and thus through the stent. Hence, with the 2 3 circular aperture increased flow from the first cardiovascular compartment into the second 4 cardiovascular compartment is provided. 5 6 In an alternative embodiment the valve may comprise 7 at least two leaflets formed from resilient material 8 which when fluid is flowing in the second direction 9 through the stent or when no fluid is flowing 10 through the stent, the leaflets are urged towards 11 each other such that the passage of fluid e.g. blood 12 is minimised. In this embodiment, movement of fluid 13 in the first direction e.g. from a first compartment 14 to a second compartment urges the leaflets of the 15 16 valve to move apart from each other enabling the passage of fluid through the stent. 17 18 The valve may be located at any position in the 19 20 stent. 21 Preferably the valve is located at either end of the 22 23 stent. 24 Such an embodiment is advantageous as a valve 25 26 portion of the stent can extend into a 27 cardiovascular compartment. This can be of 28 importance, for example, if the stent is for use 29 between the left ventricle of the heart and the 30 coronary artery as positioning of the valve in the heart muscle may restrict the movement of the valve, 31 32 as the muscle contracts and relaxes.

1 2 Preferably the valve is integral to the stent. 3 Although a stent may be located and then valve means 4 5 provided on the stent, it is preferable if the stent 6 and valve are provided in one unit such that they can be located between the cardiovascular 7 8 compartments in a single procedure. 9 10 The stent may be constructed of any suitable 11 material. 12 The stent may comprise a suitable rigid 13 14 biocompatible metal which may include, but is not limited to one or more of stainless steel, spring . 15 16 steel, Nitinol and / or a flexible resilient 17 material. 18 Preferably the stent may be constructed from 19 scaffold mesh. 20 21 22 Preferably the stent comprises a flange portion 23 located towards or at one end of the stent. 24 25 This is advantageous as when the stent is pushed 26 into tissue to provide a passage between two 27 compartments the depth of the stent in the tissue 28 can be controlled by the flange portion. If, for example, the flange portion is towards or at the 29 30 rear portion of the stent, the front portion being 31 the portion inserted first into the tissue, on 32 pushing the stent into tissue from one compartment

to another the flange provided at the rear will 1 2 prevent the stent being pushed too far into the 3 tissue, ensuring that the lumen of the stent extends from a first compartment into a second compartment. 4 Moreover the flange portion can also be used to 5 6 secure the stent in position, the tissue at around the flange preventing movement of the stent from a 7 8 first compartment to a second compartment. 9 10 In a preferred embodiment, the valve comprises at 11 least one cantilever member, having a first end and 12 a second end, said cantilever member being pivoted 13 at said first end to the stent, the cantilever 14 member being resiliently pivotable from a first 15 extended position in which the valve is in a closed 16 position to a second position in which the valve is 17 In a preferred example of such an embodiment 18 when the second end of the cantilever member is in 19 the extended position the material forming the valve 20 and defining the aperture of the valve, when in the 21 open position, is pulled such that the area of the 22 aperture formed by the material is decreased. 23 24 In such a preferred example of this embodiment, movement of fluid in a first direction through the 25 stent causes the second end of the cantilever member 26 27 to resiliently move radially inwards towards the 28 central longitudinal axis of the stent. 29 movement of the second end of the cantilever member 30 causes the material forming the valve and defining the aperture of the valve to form a larger aperture 31 32 (preferably substantially circular) in cross section

32

1 enabling increased fluid to flow through the valve. 2 As the fluid flow in the first direction is reduced or when there is no fluid flow in the first 3 direction, the cantilever member resiliently pivots 4 5 to the extended position. This movement of the 6 second end of the cantilever member to the extended 7 position causes the material forming the valve and 8 defining the aperture of the valve to be pulled to form an aperture of reduced area in cross section. 9 As the aperture has less area in cross section than 10 11 the substantially circular aperture, fluid flow in 12 both the first and second directions is restricted. 13 14 More preferably, the valve comprises two cantilever 15 In this embodiment the two cantilever 16 members are resiliently pivoted at first ends of the 17 members to the stent. When no fluid is flowing through the stent the second ends of the cantilever 18 members pivot radially outwards to an extended 19 20 position. Preferably radially greater than the circumference of the stent. When the second ends of 21 the cantilever members are in the extended positions 22 23 the material forming the valve and defining the 24 aperture of the valve when in the open position is 25 held such that the area of the aperture formed by the material is decreased and forms and ellipsoid in 26 27 cross section. 28 29 Such an embodiment may function as follows: Movement of fluid in a first direction through the stent 30 causes the second ends of the cantilever members to 31

resiliently move radially inwards towards the

central longitudinal axis of the stent. 1 movement of the second ends of the cantilever 2 members causes the material forming the valve and 3 defining the aperture of the valve to form a 4 substantially circular aperture in cross section 5 enabling blood to flow through the valve. 6 7 As the fluid flow in the first direction is reduced, 8 or when there is no fluid flow in the first 9 direction, the second ends of the cantilever members 10 again resiliently pivot to an extended position. 11 The movement of the second ends of the cantilever 12 members to their extended positions again causes the 13 material forming the valve and defining the aperture 14 of the valve to be pulled to form an ellipsoid 15 aperture of reduced area in cross section. As the 16 aperture has less area in cross section than the 17 substantially circular aperture, fluid flow in both 18 the first and second directions is restricted. 19 20 With the circular cross section increased flow 21 through the stent is enabled and with the 22 ellipsoidal cross section flow in the second 23 24 direction is minimised. 25 In such an embodiment, the aperture formed by the 26 resilient material is preferably pulled from a 27 substantially circular cross section to a 28 substantially ellipsoidal cross section, which, in 29 use, restricts the flow of fluid from a second 30 compartment toward a first compartment. 31 32

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31

Preferably the stent is constructed such that it can 1 2 be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, 3 wherein, in the collapsed configuration, the stent 4 is of narrower diameter that in the expanded 5 6 configuration. 7 8 Such a structure enables the stent to be suitably placed in the body in the narrowed collapsed 9 10 configuration and then expanded from its collapsed configuration to a fully expanded configuration. 11 12 The diameter of the stent can be increased from the 13 collapsed to expanded position using any suitable 14 procedures, for example, using a balloon angioplasty 15 16 procedure. 17 In order to position such a stent, the stent, in a 18 19 collapsed position, may be delivered to the desired 20 location in the body, for example, the heart muscle between the left ventricle and a coronary artery on 21 22 a catheter. The suitably located stents may then be 23 deployed by expanding a balloon placed in the stent such that the diameter of the stent increases from 24 25 that of the collapsed stent position to the increased diameter of the stent in the expanded 26 27 position. 28 29 Further to expanding the diameter of the stent by 30 the balloon the stent locks in the expanded

position, holding the stent against the heart muscle

1	and maintaining the stent in its expanded position
2	with increased diameter.
3	
4	The collapsed stent can be placed by suitable
5	minimally invasive techniques such as percutaneous
6	delivery.
7	
8	In an alternative embodiment the stent may be
9	constructed of material with memory such that once
10	suitably placed in the body the diameter of the
11	stent expands from a collapsed position to a fully
12	expanded position.
13	
14	For example, in such an embodiment, the stent may
15	adopt a collapsed position at low temperatures, for
16	example temperatures below body temperature, but an
17	expanded position at body temperature.
18	
19	In one preferred embodiment, the valve of the stent
20	is moved to a closed position on increasing the
21	diameter of the stent from a collapsed position to
22	an expanded position when the stent is suitably
23	positioned in the body.
24	
25	In particularly preferred embodiments the valve
26	comprises at least one cantilever member as
27	discussed above. Expansion of diameter of the stent
28	e.g. on deployment of the stent, causes the valve to
29	adopt the closed configuration.
30	
31	In this embodiment, the cantilever member may be
32	resiliently pivoted at a first end to the stent such

1 that on expansion of the diameter of the stent a 2 second end of the cantilever member pivots to an extended position in which the material forming the 3 valve and defining the aperture of the valve when in 4 the open position is pulled such that the area of 5 the aperture formed by the material is decreased. 6 7 More preferably the valve comprises two cantilever 8 members which, on deployment of the stent, cause the 9 diameter of the stent to expand from a collapsed 10 configuration in which the valve portion of the 11 stent is in an open position to an expanded 12 configuration in which the valve is in a closed 13 position. With the circular cross section increased 14 flow through the stent is enabled and with the 15 ellipsoidal cross section flow in the second 16 direction is minimised. 17 18 In such an embodiment, the aperture formed by the 19 resilient material is preferably pulled from a 20 21 substantially circular cross section to a 22 substantially ellipsoidal cross section, which, in 23 use, restricts the flow of fluid from a second 24 compartment toward a first compartment. 25 The diameter and length of the stent depends on its 26 use. For example, the stent may be of suitable 27 length to extend between the left ventricle of heart 28 29 and coronary artery. 30 Preferably the stent is two to fifteen millimetres 31 32 in diameter.

1 The stent may be constructed such that a number of 2 stents may be positioned "end to end" to increase 3 the effective length of the stent arrangment. 4 5 Thus, in one preferred embodiment the stent is 6 resiliently deformable at at least one end to 7 8 receive and enable connection with a second stent. 9 In an alternative embodiment the stent may be shaped 10 at one or both ends to enable connection to a second 11 12 stent. 13 The stent may comprise drug coatings or chemical and 14 / or mechanical coatings such as a TEFLON ™ membrane 15 16 to minimise stenosis. 17 As described above, stents of the present invention 18 may be used to link or repair two cardiovascular 19 20 compartments. 21 For example, stents of the invention may be used to 22 link a coronary artery to the left ventricle of the 23 24 heart. 25 Stents of the present invention may also be used in 26 non coronary structures e.g. non coronary veins and 27 / or arteries. 28 29 30 For example, the stents may be used to link a first portion of an ascending venous structure such as the 31 32 saphenous vein and a second portion of the same

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1	ascending venous structure. If the region between
2	the first and second portions of the femoral artery
3	is damaged or occluded, a stent of the invention may
4	be located between the first and second portions to
5	enable the movement of blood from the first portion
6	to the second portion.
7	
8	Thus in use, a stent of the present invention may be
9	provided between a first and second portion of a
10	vein e.g. a saphenous vein, to allow blood to flow
11	from the first portion to the second portion, but
12	restrict blood flow from the second portion to the
13	first portion. Such an arrangement could be used to
14	treat varicose veins.
15	
16	In a second aspect of the present invention there is
17	provided a method for treating a full or partial
18	occlusion of a blood vessel comprising the step of
19	
20	providing stent means wherein said stent means
21	comprise at least one stent of the first aspect
22	of the invention,
23	
24	a first end of the lumen of the stent means
25	being in communication with a cardiovascular
26	compartment on one side of the occlusion,
27	
28	the second end of the lumen of the stent means
29	being in communication with a cardiovascular
30	compartment on the other side of the occlusion
31	allowing blood flow from the first side to the

1	second side of the cardiovascular compartment
2	through the lumen of the stent means.
3	
4	The cardiovascular compartments on each side of the
5	occlusion may be in same the blood vessel in which
6	the occlusion is present.
7	
8	In alternative embodiments the cardiovascular
9	compartments may be different compartments, for
10	example the left ventricle of the heart and a
11	coronary artery.
12	
13	The stent means may comprise a single stent.
14	Alternatively the stent means may comprise a
15	plurality of stents longitudinally aligned to allow
16	the flow of blood from a stent at a first end of the
17	stent means to a stent at a second end of the stent
18	means.
19	
20	Preferably the stent means comprise a single stent
21	of the first aspect of the invention.
22	
23	In preferred embodiments the method further
24	comprises the step of positioning the stent means
25	between the compartments, increasing the diameter of
26	the stent means from a reduced diameter in a
27	collapsed position to an increased diameter in an
28	expanded position.
29	
30	In particularly preferred embodiments the method
31	comprises the steps of
32	

1	inserting the stent into position between a
2	first cardiovascular compartment and a second
3	cardiovascular compartment;
4	
5	expanding the diameter of the stent such that
6	the valve is moved to the closed position, but
7	can move to the open position when fluid flows
8	in a first direction from a first
9	cardiovascular compartment to a second
10	cardiovascular compartment.
11	
12	According to a further aspect of the invention there
13	is provided a method for treating varicose veins
14	comprising positioning stent means comprising at
15	least one stent of the first aspect of the invention
16	in a vein or replacing all or part of a vein with
17	stent means comprising at least one stent of the
18	first aspect of the invention.
19	
20	As above, stent means may comprise a plurality of
21	stents longitudinally aligned to allow the flow of
22	fluid from a stent at a first end of the stent means
23	to a stent at a second end of the stent means.
24	
25	As described above, in a preferred embodiment of a
26	first aspect of the invention a stent comprising a
27	valve comprising at least one cantilever member is
28	provided. The use of such a valve is not limited to
29	uses within the body. Accordingly, in a further
30	independent aspect there is provided tube means,
31	said tube means comprising a valve which comprises
32	at least one cantilever member, having a first end

1	and a second end, said cantilever member being
2	pivoted at said first end to the tube, the
3	cantilever member being resiliently pivotable from a
4	first extended position in which the valve is in a
5	closed position to a second position in which the
6	valve is open.
7	
8	Tubes comprising such valves may be used to link a
9	first cardiovascular compartment with a compartment
10	in a cardiovascular device or vice versa.
11	
12	In a further embodiment tubes comprising such valves
13	may be used to link first and second compartments in
14	a device to transport fluid, for example blood.
15	
16	For example, such tubes comprising at least one
17	cantilever member can be used in machines or devices
18	used to move fluid, for example blood, such as
19	dialysis machines.
20	
21	A further independent aspect of the present
22	invention is a device for the movement of fluid.
23	
24	Preferably the fluid is blood.
25	
26	The present invention will now be described, by way
27	of example only, with reference to the accompanying
28	figures in which;
29	
30	Figure 1 is an illustration of an embodiment of
31	a stent of the present invention extending from

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1	the left ventricle of the heart into the
2	coronary artery;
3	
4	Figure 2 is an enlarged view of an embodiment
5	of a stent of the present invention connecting
6	the left ventricle of the heart to the coronary
7	artery;
8	
9	Figure 3 is an illustration of an embodiment of
10	a stent of the present invention wherein a
11	second end of the stent is in a closed
12	position;
13	
14	Figure 4 (A) is an illustration of an
15	embodiment of a stent in a collapsed form, (B)
16	is an illustration of an embodiment of a stent
17	of the present invention in an expanded form;
18	
19	Figure 5 is an illustration of an embodiment of
20	a stent of the present invention where a second
21	end of a stent is in an open position;
22	
23	Figure 6 is an illustration of at least two
24	embodiments of stents of the present invention
25	aligned along their longitudinal axes such that
26	blood can flow from the lumen of a first stent
27	to the lumen of a second adjacent stent; and
28	
29	Figure 7 is an illustration of stents according
30	to an embodiment of the present invention
31	aligned along their longitudinal length wherein
32	the first stent has a shaped end to receive the

1 second stent and another stent is deformable to 2 receive a stent inside one end. 3 As shown in figure 1, the coronary artery 10 is 4 known to branch off the aorta 12 and be positioned 5 along the external surface of the heart wall 14. 6 7 Following oxygenation of the blood, the oxygenated 8 blood flows from the heart 16 into the aorta 12 and 9 10 onto the rest of the body. Some of the oxygenated blood is circulated along the coronary artery 10 in 11 order to oxygenate the muscles of the heart. 12 13 some individuals an occlusion is formed within the coronary artery due to plaque build up. These 14 occlusions can lead to a variety of symptoms and 15 diseases ranging from mild angina to heart attack. 16 17 In order to allow blood flow around the occlusion 18 19 within the coronary artery and to at least partially restore the flow of oxygenated blood through the 20 21 coronary artery, it is possible to bypass the 22 blocked portion of the coronary artery by providing 23 a stent 18 which extends from the left ventricle 20 of the heart into the coronary artery 10, as shown 24 in figure 2. Location of the stent 18 as shown in 25 26 figure 2 allows blood to flow unobstructed from the left ventricle 20 of the heart to the coronary 27 28 artery 10. 29 Allowing blood flow past or around occlusions of the 30 31 coronary artery 10 using a stent 18 is preferable to traditional bypass surgery in that the stent 18 may 32

1 be located and fitted using minimally invasive techniques. Generally the stents previously used to 2 3 connect the left ventricle 20 of the heart to the 4 coronary artery 10 are stents formed by hollow tubes comprising biocompatible material such as titanium 5 alloys, nickel alloys or biocompatible polymers. 6 7 These tubes may be provided and located between the left ventricle 20 of the heart and the coronary 8 artery 10 in a collapsed position and when suitably 9 located, expanded from a collapsed position to a 10 fully expanded position, using an inflatable balloon 11 catheter or other method. 12 13 14 Although such stents allow the flow of blood from 15 the left ventricle 20 of the heart into the coronary 16 artery, no artificial or mechanical means are 17 present on conventional stents to restrict the 18 backflow of blood. 19 As shown in figure 3, a stent of the present 20 invention is provided with a synthetic valve 22, one 21 example of the valve being a portion of flexible 22 23 resilient material located at the second end 24 of the stent. This flexible resilient material is 24 preferably integral with the rest of the stent. 25 26 The valve may be formed during manufacture of the 27 28 stent, prior to insertion of the stent into the 29 body. 30

31 Alternatively, as shown in the embodiment of the

32 stent in figure 4, the valve can be created by the

1 pivotal movement of cantilever members during the 2 movement of the stent from a collapsed position to an expanded position, while the stent is located in 3 the body. 4 5 6 As shown in figure 4a, in this embodiment, in a collapsed position, the resilient material, held by 7 8 two cantilever members 21, forms a substantially 9 cylindrical aperture 28. 10 11 The cantilever members are conjoined to the stent at a first end only and from the rigid biocompatible 12 metal portion 23 of the stent. On deployment 13 (expansion of diameter) of the stent, the second 14 15 ends of the cantilevers move away from each other to an extended position. This movement pulls the 16 17 resilient material such that its cross sectional 18 shape is changed from substantially circular to 19 substantially ellipsoidal. The change in the cross 20 sectional shape restricts the flow of blood in a 21 second direction from the second compartment into the first compartment through the stent. Blood flow 22 23 through the stent from a first compartment to a 24 second compartment causes the material of the 25 leaflets to be pushed such that the cantilever members resiliently move towards each other and the 26 27 aperture of the valve becomes substantially circular The area of the circular cross 28 in cross section. 29 section is larger that the ellipsoidal cross section and blood can thus easily flow from the first 30 31 compartment to the second compartment. During 32 diastole, when blood is not being pushed from the

first compartment to the second compartment, the 1 2 pressure of the blood on the material of the valve decreases. The second ends of the resilient 3 cantilever members can again move away from each 4 other and cause the valve material to form an 5 ellipsoidal cross section. 6 7 8 It can be appreciated that if more than two 9 cantilevers are used for example, three, four or 10 five cantilevers, then on deployment, the cross 11 sectional shape will not be elliptical, but 12 substantially triangular, rectangular or pentacle 13 shaped. Different shaped openings may be used as 14 appropriate to restrict the flow of blood from the 15 second compartment to the first compartment. addition, different shaped openings can be chosen to 16 17 minimise, pressure on the arterial wall caused by the 18 cantilever members. 19 20 In one embodiment, a valve formed from resilient 21 material does not require expansion of the diameter of the stent to cause the resilient material to 22 23 adopt the closed position. In this embodiment cantilever members are not required to pull the 24 25 material of the valve to a closed position and the 26 valve is manufactured in the closed position. Blood 27 flow in a first direction from the first compartment 28 towards the second compartment causes the resilient material to adopt an open position. 29 30 31 In addition to the cantilever members disclosed 32 herein, different methods of urging the resilient

1	material to a closed position following expansion of
2	a stent structure from a collapsed position can be
3	envisaged.
4	
5	During systole (contraction of the heart) the blood
6	is pumped by the heart through the stent 18 from the
7	first end 26 located at the left ventricle 20 of the
8	heart towards the second end 24 of the stent located
9	at the coronary artery. On contraction of the
10	heart, the blood of the left ventricle of the heart
11	is moved in a first direction through the stent
12	causing the valve to move from an ellipsoidal shape
13	(closed position) to an open (circular cross
14	sectional shape) position.
15	
16	In the closed position the ellipsoidal shape causes
17	the area through which blood can flow from the
18	second compartment to the first compartment to be
19	reduced to 10% the area of the open position of the
20	valve. The backflow of blood is thus reduced when
21	blood is not being pumped through the stent from the
22	first compartment to the second compartment.
23	
24	Typically reflux of blood through the valve from the
25	second compartment to the first compartment may be
26	25% that which would be expected if the valve is in
27	the open position.
28	
29	The movement of the resilient material in this
30	manner, from an ellipsoidal shape (closed position)
31	towards a circular shape (open position), increases
32	the area of the aperture 28 through which the blood

1	can flow from the first compartment (in this case
2	the left ventricle of the heart) into the second
3	compartment (in this case the coronary artery) and
4	allows the unobstructed flow of blood through the
5	valve.
6	
7	As the pressure of the blood flow through the valve
8	in a first direction decreases, the resilient
9	material is urged by the material (and in particular
10	embodiments the cantilever members of the rigid
11	portion of the stent) to cause the valve to adopt a
12	resting position, wherein the aperture of the valve
13	into the coronary artery forms an ellipsoidal shape.
14	This change in shape of the aperture reduces the
15	area of the aperture located at the second
16	compartment and minimises the blood flow from the
17	coronary artery into the left ventricle of the
18	heart.
19	
20	Movement of the stent from a collapsed position to
21	an expanded position causes the stent to be gripped
22	by the heart muscle. A flange or other projection
23	may also be provided on the stent to aid location of
24	the stent.
25	
26	As shown in figures 6 and 7 at least two stents can
27	be aligned along their longitudinal axes such that
28	blood can be communicated from the lumen of a first
29	stent to the lumen of a second adjacent stent. By
30	aligning several stents together, blood may be moved
31	from a first proximal position to a second distal
32	position, either between two different

1 cardiovascular compartments such as the left 2 ventricle of the heart and a coronary artery or within the same cardiovascular compartments such as 3 4 a blood vessel. 5 6 By aligning a number of stents along their 7 longitudinal axis it is possible to allow blood flow to be effected over a relatively large distance. 8 9 addition, as each of the stents comprise a valve, 10 the stents more closely mimic the situation in actual veins preventing the backflow of blood and 11 allowing blood to be moved upwards. An example of 12 when the blood may be required to be moved upwards 13 is in the leg of a patient when said patient is 14 15 standing. 16 17 The valves present on each of the stents allow blood 18 to be pushed through the valve on contraction of the 19 heart, but minimise the backward movement of the 20 blood during diastole. This allows blood to be 21 moved up the leg and through the body. 22 To allow the stents to be conjoined to each other, a 23 first end of a stent may be capable of deformation 24 (as shown in figure 7 (30)) to allow a second stent 25 to be partially inserted therein. Alternatively or 26 27 additionally the stent may also be widened (figure 7 28 (32)) to allow ingress of a second stent as shown in 29 figure 7. 30 31 It can be appreciated that various improvements and modifications can be made without departing from the 32

18 19

1	scope of the present invention. In particular it
2	can be envisaged that the valve may be formed from
3	at least two leaflets, which in a resting position
4	are urged towards each other minimising blood flow
5	from the second cardiovascular compartment into the
6	first cardiovascular compartment. On movement of
7	blood in a first direction through the stent, from
8	the first compartment to the second compartment,
9	these leaflets may be pushed apart from each other,
10	enabling blood flow from the first compartment into
11	the second compartment. During diastole the two
12	leaflets of the valve will be urged towards each
13	other due to the resilience of the material.
14	Alternatively, different methods may be used to
15	align the stents along their longitudinal length
16	such as providing junction means.
17	

-	Clai	
1	Clai	ans .
2	_	
3	1.	A cardiovascular stent comprising:
4		a generally tubular body, and
5		a synthetic one-way valve capable of moving
6		from a first open position to a second closed
7		position, wherein, in use, movement of fluid in
8		a first direction through the stent causes the
9		valve to adopt the open position and movement
10		of fluid in a second opposite direction causes
11		the valve to adopt the closed position.
12		·
13	2.	A cardiovascular stent as claimed in claim 1
14		wherein the valve is formed from resilient
15		material.
16		
17	3.	A cardiovascular stent as claimed in claim 2
18		wherein the valve is constructed such that, in
19		use, movement of fluid in the first direction
20		through the stent urges the resilient material
21		of the valve to adopt a configuration in which
22		the aperture defined by the material is
23		substantially circular in cross-section thereby
24		enabling increased fluid to flow through the
25		valve and thus through the stent.
26		
27	4.	A cardiovascular stent as claimed in claim 2 or
28		3 wherein the valve comprises two leaflets
29		formed from resilient material and wherein, in
30		use, when fluid is flowing in the second
31		direction through the stent or when no fluid is
32		flowing through the stent, the leaflets are

1		urged towards each other such that the passage
2		of fluid is minimised.
3		
4	5.	A cardiovascular stent as claimed in any one of
5		the preceding claims, wherein the valve
6		comprises at least one cantilever member having
7		a first end and a second end, said cantilever
8		member being pivoted at said first end to the
9		stent, the cantilever member being resiliently
10		pivotable from a first extended position in
11		which the valve is in a closed position to a
12		second position in which the valve is in the
13		open position.
14		
15	6.	A cardiovascular stent as claimed in claim 5
16		wherein the valve comprises two cantilever
17		members.
18		
19	7.	A cardiovascular stent as claimed in any one of
20		the preceding claims wherein the stent is
21		constructed such that it can be expanded in
22		diameter from a "collapsed" configuration to an
23		"expanded" configuration, wherein in the
24		collapsed configuration, the stent is of
25		narrower diameter than in the expanded
26		configuration.
27		·
28	8.	A cardiovascular stent as claimed in claim 7
29		when dependent on claim 5 or claim 6 wherein on
30		expansion of the diameter of the stent, the
31		second end of the cantilever member pivots to
32		an extended position in which the material

3		the valve when in the open position is pulled
A		such that the area of the aperture formed by
4		the material is decreased.
5		
6	9.	A cardiovascular stent as claimed in any one of
7		the preceding claims wherein the stent is
8		resiliently deformable at one or both ends to
9		receive and enable connection with a second
10		stent.
11		
12	10.	A cardiovascular stent as claimed in any of one
13		of the preceding claims wherein the stent is
14		shaped at one or both ends to enable connection
15		to a second stent.
16		
17	11.	A cardiovascular stent as claimed in any one of
18		the preceding claims for linking a coronary
19		artery to the left ventricle of the heart.
20		
21	12.	A cardiovascular stent as claimed in any one of
22		claims 1 to 10 for linking a first portion of
23		an ascending venous structure and a second
24		portion of the same ascending venous structure.
25		
26	13.	A method for treating a full or partial
27		occlusion of a blood vessel comprising the
28		steps of:
29		
30		providing stent means wherein said stent means
31		comprise at least one stent as claimed in
		claims 1 to 12, a first end of the lumen of the

1		stent means being in communication with a
.2		cardiovascular compartment on a first side of
3		the occlusion,
4		
5		the second end of the lumen of the stent means
6		being in communication with a cardiovascular
7		compartment on the other side of the occlusion
8		and allowing blood flow from the first side of
9		the occlusion to the other side of the
10		cardiovascular compartment through the lumen of
11		the stent means.
12		
13		
14	14.	A method as claimed in claim 13 wherein the
15		stent means comprises a plurality of stents
16		longitudinally aligned to allow the flow of
17		blood from a stent at a first end of the stent
18		means to a stent at a second end of the stent
19		means.
20		
21	15.	A method as claimed in claim 13 or claim 14
22		further comprising the step of increasing the
23		diameter of the stent from a reduced diameter
24		in a collapsed position to an increased
25		diameter in an expanded position.
26		
27	16.	A method for treating varicose veins comprising
28		the step of:
29		
30		positioning stent means comprising at least one
31		stent as claimed in claims 1 to 12 in a vein.
2		

1	17.	A method for treating varicose veins comprising
2		the step of:
3		<u>.                                    </u>
4		replacing at least a part of a vein with stent
5		means comprising at least one stent of the
6		first aspect of the invention.
7		
8	18.	Tube means comprising a tubular portion and a
9		valve, said valve comprising at least one
1.0		cantilever member having a first end and a
11		second end, said cantilever member being
12		pivoted at said first end to the tubular
13		portion, the cantilever member being
14		resiliently pivotable from a first extended
15		position in which the valve is in the closed
16		position to a second position in which the
17		valve is in the open position.
18		
19	19.	Tube means as claimed in claim 18 wherein in
20		moving from the closed position to the open
21		position the aperture of the valve is moved
22		from being ellipisoidal to substantially
23		circular.
24		
25	20.	A device for moving fluid comprising a tube as
26		claimed in claims 18 or 19.
27		
28		

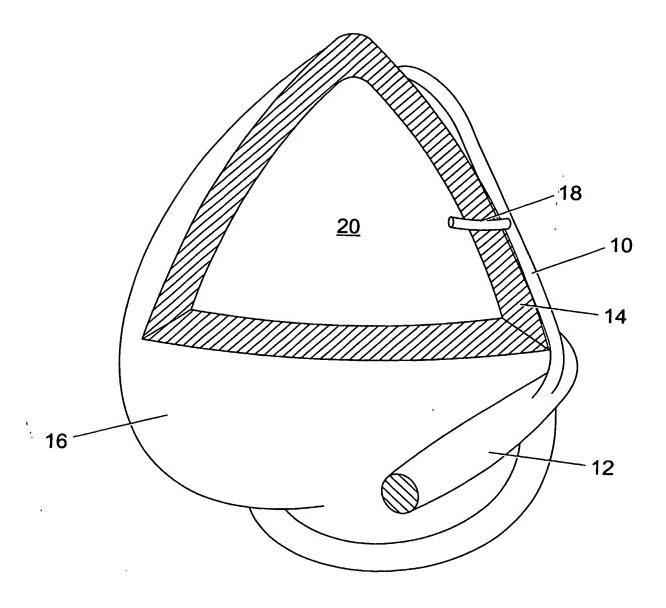


Fig. 1

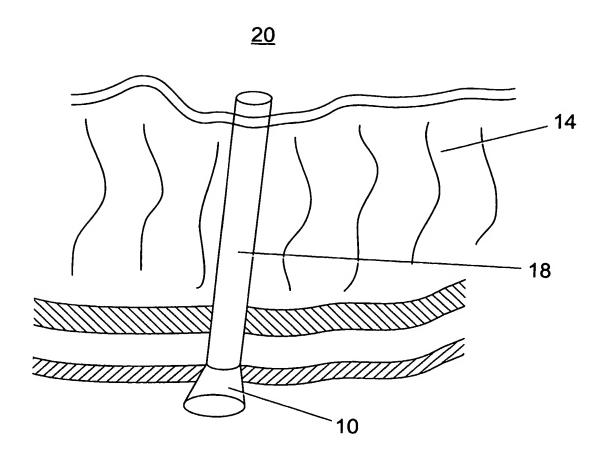


Fig. 2

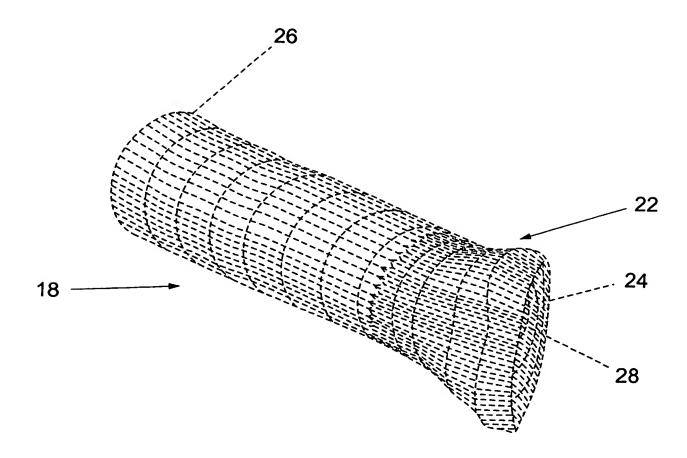
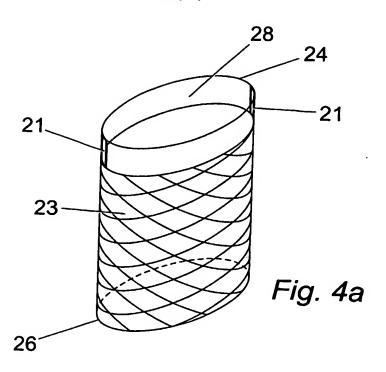
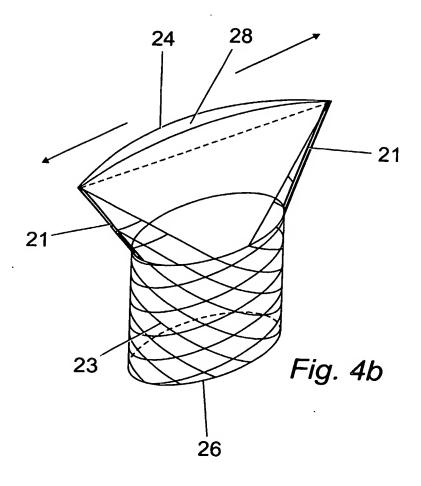


Fig. 3







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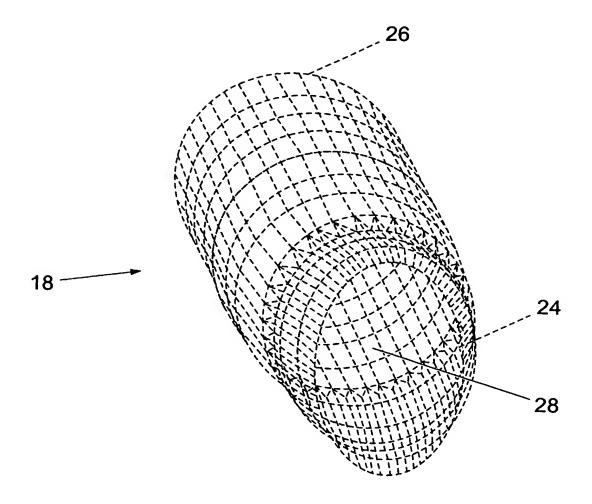


Fig. 5

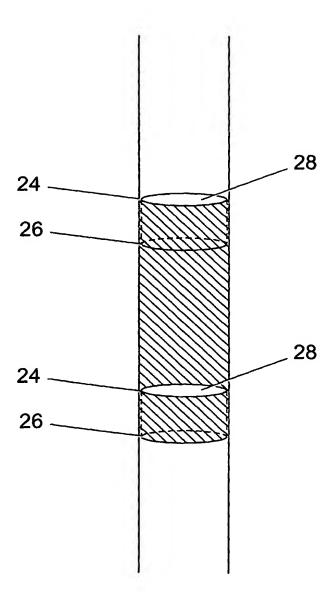


Fig. 6

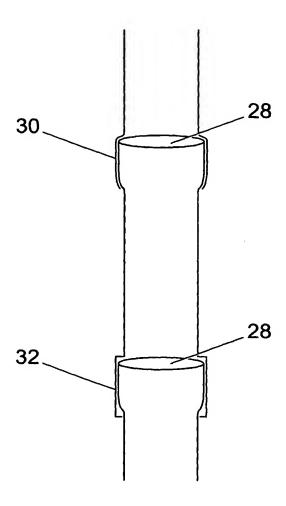


Fig. 7

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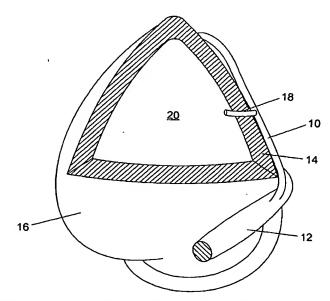
- (88) Date of publication of the international search report: 12 August 2004
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[Continued on next page]

(54) Title: BLOOD REGULATION DEVICE



(57) Abstract: The present invention relates to a cardiovascular stent (18) including a generally tubular body and a synthetic valve (22) capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

#### INTERNATIONAL SEARCH REPORT

national Application No PCT/GB 03/03810

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/24 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 **A61F** Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal C. DOCUMENTS CONSIDERED TO BE RELEVANT Cilation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X US 2002/165606 A1 (SANTAMORE WILLIAM ET 1-7,11, AL) 7 November 2002 (2002-11-07) 12,18,20 19 paragraph '0034! Α 8-10 paragraph '0002! paragraph '0009! - paragraph '0011! paragraph '0028! paragraph '0038! paragraph '0042! - paragraph '0045! figures 1A-4 Υ US 4 759 758 A (GABBAY SHLOMO) 19 26 July 1988 (1988-07-26) column 4, line 1 - line 30 figures 7,9,10 Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the 'A' document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled 'O' document referring to an oral disclosure, use, exhibition or 'P' document published prior to the international filing date but later than the priority date claimed in the art. "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 11 May 2004 19/05/2004 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx. 31 651 epo nl, Amaro, H Fax: (+31-70) 340-3016



nternational application No. PCT/GB 03/03810

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inter	national Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: $13-17$ because they relate to subject matter not required to be searched by this Authority, namely:
	Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
j,	Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
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Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This inter	national Searching Authority found multiple inventions in this international application, as follows:
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4. 🔲	No required additional search fees were timely paid by the applicant. Consequently, this international Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark o	The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.



national Application No

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